Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3064-P
P.O. Box 8015
Baltimore, MD 21244-8015

March 31, 2005

"Recertification and Competition" 486.316

As Board Member of The Transplant Resource Center of Maryland, I am writing to update you about recent regulatory developments that may severely undermine a critical Department of Health and Human Services (HHS) initiative. Recently proposed regulatory actions by the Centers for Medicare and Medicare Services (CMS) may harm rather than help the almost 90, 000 Americans and over 2400 citizens waiting for organ transplants in Maryland.

The Organ Donation Breakthrough Collaborative has engaged the Organ Procurement Organization (OPO) community and the nations' largest hospitals to increase the number of organs available for transplant. The Transplant Resource Center of Maryland is apart of this exciting initiative that relies on joint accountability and an integrated partnership between OPO's and participating hospitals. The model aims at implementing best practices for increasing the rates of organ donation.

The Organ Donation Breakthrough Collaborative has achieved extraordinary results in the past 12 -18 months. Nationally, the number of deceased organ donors has increased by nearly 11%, and contributed to increases of more than 20% in Maryland. In fact, this collaborative model has been widely studied and cited by the greater healthcare quality improvement community for its effectiveness.

As our hospitals and the Transplant Resource Center of Maryland have worked together as a team over the past year and a half, we have accomplished phenomenal things.

We have some of the busiest trauma centers in the country and have successful transplant programs that rely on the relationships forged by the OPO and the hospital staff.

CMS is proposing an untested, theoretical, competitive model in which every OPO would be completing every four years to continue its service area. This competitive model has the potential of stifling the sharing of best practices between OPO's that have been developed and fostered through the Organ Donation Breakthrough Collaborative.

We are proud to say that our team has increased the conversion rates at our OPO to 62%. This success which has saved an addition 100 lives through the provision of addition organs available for transplantation from 2003 to 2004. Some of these gains can be

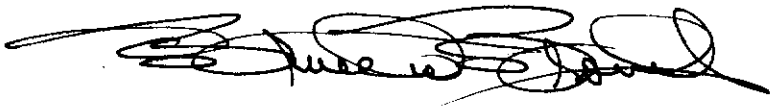
attributed to the exceptional sharing of information across OPO's and hospitals to understand what is working to increase conversion rates in different parts of the country. Sharing best practices is the hallmark of this program. The Transplant Resource Center of Maryland staff has built relationships with hospital, legislative, and regulatory leaders that bridge the gaps that had existed in the past.

The Collaborative Team has used strategies and change concepts to create opportunities in the donation process.

1. Developed clinical trigger criteria – making referrals more timely and consistent.
2. Increase timely death record reviews so that missed opportunities could be addressed.
3. Identified high level hospital "champions" to put organ donation on the priority list for our hospital.
4. Further developed our DCD protocols
5. Continued to model one of the most effective consent processes in the country

As a Board member of the OPO who has been involved with the important work of increasing the number of organs available for transplant, we strongly support the Collaborative model in place of the untested competitive model that CMS proposes in the rule.

Sincerely,



Bruce W. Brooks
Board Member, Vice Chair
Transplant Resource Center of Maryland

JOHNS HOPKINS
UNIVERSITY

Immunogenetics Laboratory
School of Medicine
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Baltimore MD 21205-2222
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Andrea A. Zachary, Ph.D.
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March 30, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3064-P
P.O. Box 8015
Baltimore, MD 21244-8015

RE: "Recertification and Competition" 486.316

To Whom It May Concern:

As a member of the Board of Trustees of The Transplant Resource Center of Maryland, I am writing to update you about recent regulatory developments that may severely undermine a critical Department of Health and Human Services (HHS) initiative. Recently proposed regulatory actions by the Centers for Medicare and Medicare Services (CMS) may harm rather than help the almost 90, 000 Americans and over 2400 citizens waiting for organ transplants in Maryland.

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Transplant Resource Center of Maryland and the hospitals, working together as a team over the past year and a half, have accomplished phenomenal things.

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CMS is proposing an untested, theoretical, competitive model in which every OPO would be competing every four years to continue its service area. This competitive model has the potential of stifling the sharing of best practices between OPO's that have been developed and fostered through the Organ Donation Breakthrough Collaborative.

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The Collaborative Team has used strategies and changed concepts to create opportunities in the donation process. These strategies include:

1. Developed clinical trigger criteria – making referrals more timely and consistent
2. Increase timely death record reviews so that missed opportunities could be addressed
3. Identified high level hospital "champions" to put organ donation on the priority list for our hospital
4. Further developed our DCD protocols
5. Continued to model one of the most effective consent processes in the country

As a Trustee of the OPO that has been involved with the important work of increasing the number of organs available for transplant, I strongly support the Collaborative model in place of the untested competitive model that CMS proposes in the rule.

Sincerely,

Andrea A. Zachary

Andrea A. Zachary, Ph.D.

LifeLink
HealthCare Institute

Advanced medical, surgical & transplant patient care

March 31, 2005

Centers For Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3064-P
P.O. Box 8015
Baltimore, Maryland 21244-8015

HARDCOPIES SENT VIA U.S. MAIL

Response Comments Regarding CMS Proposed Regulations On:
"Outcome Measures" (DCD) §486.318

As the Surgical Director of the Tampa General Hospital/LifeLink Renal Transplant Program and Medical Director of the LifeLink HealthCare Institute, I wish to support and affirm the CMS position in the proposed regulations that the standard definition of Organ Donor Potential should only include those deaths from neurological causes and exclude donors resulting from Donation After Cardiac Death (DCD).

42CRF §486.318 states: "Standardized Definition of Organ Donor Potential"

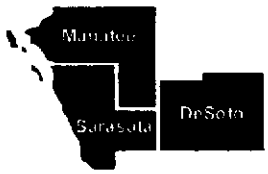
"We propose limiting the definition to include only deaths from neurological causes (that is, brain death) rather than including non-heart beating donation (also called donation after cardiac death (DCD))."

Our Renal Transplant Program supports the concept of DCD organs but has not utilized any organs from such donors. I have had previous experience with "Non-Heart Beating Donors" and know that these organs do not function as well as traditional non-expanded donor organs. I view DCD organs as still experimental and we need more scientific facts and long-term follow-up before we can honestly assure our patients that utilization of these kidneys is in their best interest long-term.

I strongly believe that only death by neurological criteria organs should be used to define organ donor potential and the unproven DCD organs should not be used in the accounting measure to determine OPO performance.

Respectfully,

Victor D. Bowers, M.D., FACS
Surgical Director
Tampa General Hospital/LifeLink HealthCare Institute
Renal Transplant Program



DISTRICT TWELVE MEDICAL EXAMINER

1762 Hawthorne Street, Suite 5, Sarasota, FL 34239-2100 • Phone: (941) 361-6909 Fax: (941) 361-6914

March 28, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3064-P
P.O. Box 8015
Baltimore, MD 21244-8015

HARDCOPIES SENT VIA U.S. MAIL

Response Comments Regarding CMS Proposed Regulations On:
"Relationships with Tissue Banks" §486.322

As Chief Medical Examiner for Florida's Twelfth District (Sarasota), I am writing to comment on the proposed CMS regulation, which I feel may adversely affect the operations of my office.

42CFR §486.322 states *"We propose requiring OPOs to have arrangements with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements to cooperate in the following activities, as may be appropriate, to assure that all usable tissues are obtained from potential donors...(2) Obtaining informed consent from families of potential tissue donors in the absence of a donor document; and..."*

The District Twelve Medical Examiner's office shares the responsibility with health care professionals to meet the transplant needs of our local community. The OPO with whom we work, Lifelink of Florida, has, in my experience, always maintained the highest standards of ethical and compassionate professional conduct. Such standards are crucial in assuring that the needs of my office are met while providing families the opportunity to donate. Many tissue banks may not share the same high standards as Lifelink and other OPOs regarding consent, recovery and reconstruction of the body in accordance with the wishes of the donor family. Thus, although I am in favor of cooperative arrangements between all parties involved with the process of organ and tissue donation, including OPOs and tissue banks, I do not feel that any OPO should be forced to work with a tissue bank whose practices are not consistent with that of the OPO. The proposed regulation would effectively require OPO's, and by extension, my office, to work with tissue banks that may not share the high standards that I and the citizens of my district have come to expect and deserve.

Our current agreement and longtime relationship with LifeLink of Florida has been one of mutual cooperation and respect. This relationship ensures that each potential donor, even among medical examiner cases, is evaluated for medical suitability for donation and that the family of each potential donor is notified of their option to donate.

Thank you for your consideration.

Respectfully,

Russell S. Vega

4 April 2005

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3064-P
7500 Security Boulevard
Baltimore, Maryland 21244-1850

To Whom It May Concern:

I would like to take this opportunity to respond to the propose rules 42 CFR 413,4441,486, and 498 addressing Conditions and Coverage for Organ Procurement Organization. I have been involved in the field of transplantation since 1982, working as a coordinator, perfusionist, and researcher having seen many changes to this field. I would lie to thank you for the opportunity to respond to the proposed rules and hope that maybe some of my suggestions will be implemented.

I believe that all who have been involved in preparing this document have both the donor families and potential recipients best interest at the center of this proposal. However, I believe this proposal is just the beginning and more aggressive proposals to explore the utilization of DCD (Uncontrolled Non-Heart Beating Donors) needs to be further expanded is probably the only effective way to reduce the donor shortage.

Outcome Measures (486.318)
This is a reasonable proposal especially allowing OPO's to allow the research organs to be counted towards the recertification of OPO's. In so allowing this one statement organs that cannot currently be transplanted at the present time may allow the researchers, either from non-profits or for profit, research programs to develop experimental techniques that could lead to new procedures that could assist in reducing the transplant waiting list.

Administration and Governing Body (486.324)
Transplant Surgeons or Transplant Hospital staff should not be allowed to dictate to the OPO whom the OPO would like to hire, especially if the person to be hired is a well qualified person and has stood up to a single institution and demanded the patient care needs to have a higher priority than a single transplant centers having a higher priority over the other transplant centers.

Further when a local OPO is allocating an organ for transplant, especially kidneys, and there are multiple transplant centers in the OPO region transplant surgeons should not be allowed to stall or lengthen the preservation time in order to transplant one of their patients over the other transplant patients on other transplant programs waiting list. This practice probably should be further explored and regional tissue typing laboratories be established and transplant programs tissue typing labs be merged together to form a regional tissue typing laboratory.

On page 6108 it is stated that in-depth training is particularly critical, is true but each OPO uses their own type of training, which is very expensive and does not provide a standard procedure to train. There should be a standard curriculum to train staff that will be talking to families to obtain consent, standard training and certification for managing donors, standard training and certification for recovery and packaging or organs, and standard training and certification of perfusion of organs after the organ has been recovered. International

Society for Organ Preservation (ISOP) has established training and certification for both recovery and packaging of organs along with perfusion of the organs. The certification group of technicians from the 2004 exam had 2 out of 7 individuals pass the UNOS 5.0 requirements for packaging of organs and 3 out of 6 for perfusion of organs. There needs to be a national standard for both sections using modern scientific standards that will establish these standards. It has been published by Sonneday, Montgomery, and et al. that there are differences in the way OPO's perfuse kidneys. Transplantation 2003; 75:2029-2033. Also, Futon, Conte, et al. has shown by DNA analysis that after 4 hours of cold storage the mitochondria cells have lost all the ATP substrate compared to 24 hours of perfusion. Clinical Transplantation 2004; 18 Supplementary 12:22-27. There are other articles that concur with these two articles. ISOP is willing to establish perfusion and packaging standards and training for both cold storage and perfusion of organs.

Condition: Information Management 486.330:
On page 6131 there is the incident from North Carolina and Illinois that resulted in death of two recipients because of errors in identification of organs. Organs are like units of blood or blood products. When units of blood or blood products are transfused two individuals check the unit before and during processing and at the administration of the blood or blood product the unit is also double-checked and the signatures are sent and stored in the blood bank. However, in the transplant field there is no documentation of the donor to the recipient. I propose that the following example be implemented:

Donor Demographic

UNOS Identification #_____ Donor ABO: _____

Organ Type:

Donor Name: _____

Recovery Surgeon: _____

OPO Coordinator or O.R. Recovery Technician: _____

Verified Date: _____ Verified Time: _____

Recipient Demographics

Recipient UNOS Identification # _____ Recipient ABO: _____

Recipient Name: _____

Transplant Surgeon: _____

OR Personnel: _____

Verified Date: _____ Verified Time: _____

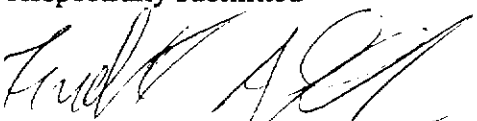
This form will be copied and sent to UNOS to be placed with UNOS donor documentation and a copy maintained at the transplanting OPO.

Page 6114 Dealing with errors it appears that there are under reporting of mislabeled or not labeled organs for transporting. UNOS policy states that the label is to be placed on the transportation container but on average I have seen approximately 10% of the organs imported into the perfusion lab as being mislabeled or not labeled, or incorrect donor paper work, or incomplete paperwork. Anytime there is a discrepancy with the organ UNOS should be the contact center to straighten out and report this error. Also certain OPOs are blanking out the donor name, social security number and other identifiers, which does not allow for the verification of the organ. There must be enforceable consequence that if there is a continuation of this type of practice immediate de-certification should be implemented even if the OPO is meeting the established criteria to maintain the certification of the OPO.

Thank you for allowing me to comment on these proposed OPO rule changes. If you would like to contact me concerning my comments I can be reached at:

Fred Gage
11104 Lund Place
Kensington, Maryland 20895
Phone 240-508-6779
e-mail: fredgage@juno.com

Respectfully submitted



Frederick A. Gage, Ph.D.

Hillsborough County
Florida

Office of the County Administrator
Patricia G. Bean

March 28, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3064-P
PostOffice Box 8015
Baltimore, Maryland 21244-8015

HARDCOPY SENT VIA U.S. MAIL

Re: Response comments regarding CMS proposed regulation, "Relationships with Tissue Banks" §486.322

Ladies and Gentlemen:

I am writing to object to proposed rule 42 CFR §486.322 which states:

> We propose requiring OPOs to have arrangements with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements to cooperate in the following activities, as may be appropriate, to assure that all usable tissues are obtained from potential donors...(2) Obtaining informed consent from families of potential tissue donors in the absence of a donor document; and...

Like my clinical colleagues and those who lead our local hospitals, I feel a responsibility to meet the organ transplantation needs and banked tissue requirements of sick patients. I have seen first-hand the excellent work that stems from a cooperative arrangement between an OPO and a tissue bank. As a medical examiner I am free to dissociate myself from a tissue bank that does inadequate reconstruction of limbs after long bone donation, or takes tissue that neither I nor the family approved. Similarly, I do not think that an OPO should be required to obtain consent for a tissue bank whose practices are substandard in critical areas such as consent. Cooperative arrangements cannot be forced. They are grown and nurtured. I urge you to delete the above-cited proposal.

Respectfully,

Vernard I. Adams, MD
Chief Medical Examiner

March 28, 2005

LEE MEMORIAL
HEALTH SYSTEM

P.O. BOX 2218

FORT MYERS, FLORIDA 33902

239.332.1111

CAPE CORAL HOSPITAL

HEALTHPARK CARE CENTER

HEALTHPARK MEDICAL CENTER

HEALTHPARK OF THE ISLANDS

LEE CONVENIENT CARE

LEE MEMORIAL HOSPITAL

LEE PHYSICIAN GROUP

THE CHILDREN'S HOSPITAL

THE REHABILITATION HOSPITAL

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3064-P
P.O. Box 8015
Baltimore, MD 21244-8015

Recertification and Competition" §486.316

Florida, I would like to weigh in on the above referenced section of proposed CMS rule 3064-P: Conditions for Coverage for Organ Procurement Organizations. Specifically, while this proposal appears to have the intent of strengthening and consolidating strong performing OPOs, I believe the proposed conditions will precipitate a competitive environment throughout the OPO community – a philosophy that is in direct opposition to the successful HHS Collaborative efforts instituted this year. I strongly oppose any framework that encourages a certified OPO to take over the service area of another certified OPO, thereby demotivating all OPOs from sharing best practices.

Lee Memorial is a 400 bed, level-2 trauma center that covers 7 counties. A survey conducted by the Organ Procurement and Transplant Network between 2002 and 2003 ranked Lee Memorial 180th in the nation for eligible donor potential. We found this rank unacceptable to us and, looking internally, we discovered that we were only converting at rate of 47%. Understanding the importance of increasing that rate, we decided to partner with LifeLink of Florida to participate in the HHS Organ Donation Breakthrough Collaborative initiative. It was through this participation that we were able to identify multiple 'best practices' that, to date, have resulted in an increase in our conversion rate to 59%, with a goal of sustaining this momentum to reach a rate of 75%. The impact of this regulation threatens the sharing of best practices between hospitals and throughout the nation and, I believe, will result in decreased donation and transplantation rates!

I therefore want to register my strong opposition to creating a nationally competitive OPO environment. Decertification of non-performing OPOs is a different matter and necessary in the overall plan to increase donor potential wherever possible, but decertification of OPOs that meet the standards serves no positive purpose – certainly not for this hospital. We request that you consider adopting a collaborative model instead of the competitive model currently proposed.

Sincerely,

Davy Crockett

Davy Crockett, RN, MPA, CHE, CNAA, BC
Vice President, Patient Care Services
Lee Memorial Hospital

OFFICE OF THE DISTRICT MEDICAL EXAMINER
DISTRICT 21, STATE OF FLORIDA
LEE-HENDRY-GLADES COUNTIES

70 DANLEY DRIVE
FORT MYERS, FLORIDA 33907-2437

Phone #(239) 277-5020
Fax # (239) 277-5017
Suncom # 729-5020

Rebecca A. Hamilton, M.D.
District Medical Examiner

March 25, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3064-P
P.O. Box 8015
Baltimore, MD 21244-8015

HARDCOPIES SENT VIA U.S. MAIL

Response Comments Regarding CMS Regulations On:
"Relationships with Tissue Banks" §486.322

As Medical Examiner for Lee County, Florida, and a strong supporter of organ and tissue donation, I would like to convey my concern regarding the proposed CMS regulation, which may interfere with our investigations as well as negatively affect organ/tissue recoveries, falling within our jurisdiction.

42CFR §486.322 states *"We propose requiring OPOS to have arrangements with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements to cooperate in the following activities, as may be appropriate, to assure that all usable tissues are obtained from potential donors...(2) obtaining informed consent from families of potential tissue donors in the absence of a donor document; and..."*

We have confidently worked with LifeLink to facilitate the wishes of donors and their families for a number of years. LifeLink's highly trained personnel secure informed consent, coordinate the recovery process and maintain close communication with, and respect for, the protocols of my office. It is our obligation as a public servant to facilitate the recovery of organs and tissue from individuals who wish to donate, while maintaining the integrity of our forensic investigation.

Routinely clearance is provided for organ/tissue donation and we take abundant steps to assure every medically suitable organ/tissue is cleared for recovery and transplantation. This is accomplished through intensive communication and long-standing procedures, which have been developed over many years while working with our current tissue bank. To date, we choose to only have such a relationship with LifeLink, despite requests by other tissue recovery agencies over the last several years.

The informed consent process is of particular interest and concern to my associates and me. If the intention of this regulation is to require an OPO to request and obtain an informed consent of behalf of a tissue bank that does not share the same policies/practice, my office, as well as the OPO, could be placed in a difficult legal and ethical position. My associates and I may also be placed in the difficult position of selectively releasing tissue based on our knowledge, or lack thereof, depending on the consent and recovery practices of each tissue bank. This will cause an undue increase in work for my staff, and as a public entity, this will not best serve my community.

OPOs should not be forced to work with just any tissue bank willing to work with them. The "gate-keeper" role and passing of referrals to the hospital's chosen entity as their tissue provider are appropriate functions for OPOs. Any additional requirement or cooperation should only occur when there is a formal and collaborative agreement between the OPO and tissue bank(s), helping us to fulfill donor families' wishes, while maintaining our communities best interests for unhampered forensic investigations.

Respectfully,

Rebecca Hamilton, MD
Chief Medical Examiner, District 21

University of Maryland Medical Center

R ADAMS COWLEY
SHOCK TRAUMA CENTER

Thomas M. Scalea, M.D.
Physician-in-Chief
Shock Trauma Center
Francis X. Kelly/MBNA Professor of
Trauma Surgery
Director, Program in Trauma
University of Maryland School of Medicine

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3064-P
P.O. Box 8015
Baltimore, MD 21244-8015

"Recertification and Competition" 486.316

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4. Further developed our DCD protocols
5. Continued to model one of the most effective consent processes in the country

As a Board member of the OPO who has been involved with the important work of increasing the number of organs available for transplant, we strongly support the Collaborative model in place of the untested competitive model that CMS proposes in the rule.

Sincerely,

T. Scalea

Transplant Resource Center of Maryland
Board Member

Central Florida Lions Eye & Tissue Bank, Inc.

18

March 24, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3064-P
P.O. Box 8015
Baltimore, MD 21244-8015

HARDCOPIES SENT VIA U.S. MAIL

Response Comments Regarding CMS Proposed Regulations On:
"Relationships with Tissue Banks and Requesting Consent" §486.322

As the Executive Director/CEO of Central Florida Lions Eye and Tissue Bank, currently the largest eye bank in the world, I read with interest the CMS proposed regulations for OPO's. I feel compelled to express my concern on the section that relates to OPO relationships with tissue banks, specifically with tissue banks that they do not have a working relationship with.

42CFR §486.322 states:
"We propose requiring OPOs to have arrangements with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements to cooperate in the following activities, as may be appropriate, to assure that all usable tissues are obtained from potential donors...(2) Obtaining informed consent from families of potential tissue donors in the absence of a donor document; and..."

The Central Florida Lions Eye and Tissue Bank has established formal working relationships with several OPO's. It is through these formal relationships, which are based on mutual accountability, trust and true working partnerships that our eye bank has become the single largest source of corneas for transplant in the world. Clearly, formal working relationships, in which both parties agree to work together and to fulfill each others expectations as it relates to consent and recovery practices provides the best level of service to both waiting recipients and donor families. Because many tissue and eye banks do not share the same philosophy regarding consent, recovery and reconstruction practices as the OPO or other tissue or eye bank, the OPO should not be forced to obtain consent for a tissue bank that it does not want to work with.

Thank you for providing the opportunity to comment on these proposed regulations.

Respectfully,

Jason Woody
Executive Director/CEO

5523 W. Cypress St. • Suite 100 • Tampa, FL 33607
Tel. (813) 289-1200 • Fax (813) 289-1800

New Jersey Center for Biomaterials

Sponsored by Rutgers–the State University of New Jersey,
the University of Medicine and Dentistry of New Jersey, and New Jersey Institute of Technology

Professor Joachim Kohn, Director

March 29, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3064-P
P.O. Box 8015
Baltimore, MD 21244-8015

Dear Sir or Madame:

I am writing to you in my capacity as the Director of the New Jersey Center for Biomaterials, a not-for-profit consortium of the public Universities of New Jersey. As an expert in biomaterials science, tissue regeneration, and the use of human tissue in medical therapies, I urge you to remove the language within the Centers for Medicare & Medicaid Services proposed rulemaking (42 CFR Part 486, Section 486.342, item 2), which states that minimum requirements for consent for tissue donation should include "Information (such as for-profit or non-profit status) about organizations that will recover, process and distribute..." donated tissue.

Each year, donated tissue is utilized in thousands of musculoskeletal surgeries that alleviate pain and restore function. In spite of a vigorous research effort of the biomaterials community, many patients have currently no medically equivalent alternative to the use of human-derived tissue. Therefore, the generous gift of tissue donation and the enhancement of that gift through the complex technologies developed predominantly by for-profit companies are of critical importance to a very large number of patients.

A completely not-for-profit system that is capable of meeting the demands and needs of patients requiring musculoskeletal tissue transplantation does not exist. Our tissue banking system is inherently a combination of for-profit and not-for-profit companies, and the ability to transplant musculoskeletal tissue extends far beyond recovery, processing and distribution, as defined in the proposed rule.

I believe that the proposed language is misleading and confusing to consenting individuals who are often making a personally difficult decision at a time of great emotional stress. Inevitably, if the proposed language is adopted, consenting individuals will choose to restrict the use of their loved ones' tissue by for-profit companies, based on the erroneous belief that not-for-profit companies would somehow be more deserving of the gift of donation. In fact, as mentioned above, for-profit and not-for-profit organizations coexist within the tissue banking system, charge similar fees, and operate under the same ethical guidelines. By restricting the amount of tissue sent to for-profit companies, patients will be needlessly deprived of the benefit of complex processing technologies that add clinical value to those tissues and that are predominantly available through the services of for-profit companies.

Consequently, reducing the volume of tissue available to for-profit companies will result in a decrease in the number of tissue banks, a decrease in therapeutic options open to physicians, a rise in the cost of tissue to hospitals, and a decrease in technological advances that arise from research and development conducted by for-profit companies, with the aim of improving patient outcomes.

The proposed rule, with regard to its inclusion of "such as for-profit or nonprofit" has no benefit to patients, is misleading to consenting individuals, and is potentially detrimental to the effectiveness of the tissue banking community and to the medical community which it serves.

I respectfully request that the proposed CMS rule change not be adopted as written.

Sincerely,

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